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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,810	04/12/2004	Jennifer Lynne Reed	IL500US	5467

36577 7590 04/15/2008

JOHNATHAN KLEIN-EVANS
ONE MEDIMMUNE WAY
GAITHERSBURG, MD 20878

EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
04/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,810	REED, JENNIFER LYNNE	
	Examiner	Art Unit	
	GYAN CHANDRA	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,8-11,15-25,27,28 and 37-40* is/are pending in the application.

4a) Of the above claim(s) *5,11,16-19,21,22 and 25* is/are withdrawn from consideration.

5)☒ Claim(s) *3 and 4* is/are allowed.

6)☒ Claim(s) *1,8-10,15 and 24* is/are rejected.

7)☒ Claim(s) *20,23,27,28 and 37-40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/25/07; 10/31/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1, 3, 4, 8-10, 15, 20 23-25, 27, 28 and 37-40) in the reply filed on 3/7/2008 is acknowledged. The traversal is on the ground(s) that the polypeptide of SEQ ID NO: 27 comprises a VH CDR1 (SEQ ID NO: 26), VH CDR2 (SEQ ID NO: 64) and VH CDR3 (SEQ ID NO: 3) and similarly a polypeptide of SEQ ID NO: 28 comprises a VL CDR1 (SEQ ID NO: 65), CDR2 (SEQ ID NO: 66) and CDR3 (SEQ ID NO: 20); and therefore, search results of the polypeptide of SEQ ID NO: 27 or 28 would necessarily produce search results for VL CDRs and VH CDRs. This is found persuasive and therefore, Group I and II would be examined together.

The requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, And/Or Claims

Claims 1, 3-5, 8-11, 15-25, 27, 28, and 37-40 are pending.

Claim 5 is withdrawn and claims 11, 16-19, 21, 22 and 25 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. It is noted that claim 25 was withdrawn from examination for the reasons of record on page 2 of the Office Action of 5/1/2007 (for being drawn to a non-elected invention). Therefore, Applicant does not comply in identifying claim 25 which should be labeled - (withdrawn).

Claims 1, 3, 4, 8-10, 15, 20, 23-24, 27, 28, and 37-40 are being examined to the extent they read on the elected species (i.e., influenza virus).

Claim Objections

Claims 9-10 are objected for reciting non-elected inventions (i.e., a bacterial infection, a fungal infection, a metapneumonia virus or a parainfluenza virus infection).

Claims 20, 23, 27, 28 are objected for depending from a withdrawn claim (i.e., claim 5).

Appropriate correction is required.

Response to Arguments

Claim Rejections - *withdrawn*

Claim Rejections - 35 USC § 112-*enablement*

The rejection of claims 1, 3, 4, 8-10, 15, 20, 23-24, 27 and 28 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering an IL-9 antagonist to treat or ameliorate a respiratory infection, wheezing, asthma or an allergy in human subject, does not reasonably provide enablement for preventing or managing a respiratory infection, wheezing, asthma or an allergy in huan subject a human child or preterm infant is withdrawn in view of Applicants deletion of terms “preventing” or “managing”.

Claim Rejections - 35 USC § 103

The rejection of claims 3-4, 20 and 27 under 35 U.S.C. 103(a) as being unpatentable over Levitt et al. (2001) in view of Skoner (Pediatrics 109: 381-392, 2002) is withdrawn in view of Applicants' amendment of claims 3-4 to recite "an antibody or fragment comprising a VH CDR1 comprising the amino acid sequence of SEQ ID NO: 26....., and a VL domain comprising the amino acid sequence of SEQ ID NO: 28".

***Claim Rejections** – maintained*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

It is noted that the limitation of claim 24 which is taught by levitt et al under 35 USC 102 was inadvertently included with claims rejected under 35 USC 103. Therefore, the rejection of claim 24 under 103 is withdrawn and is now being included with the rejection under US 35 USC 102(b).

Claim 1 remains rejected and claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Levitt et al. (US Patent No. 6,261,559, published on 7/17/2001) for the reasons of record on pages 8-9 of the Office Action of 5/1/2007.

Claims 1 and 24 are broadly drawn to a method of treating or ameliorating a respiratory infection or a symptom thereof in a human subject suffering therefrom,

said method comprising administering an effective amount of an IL-9 antagonist to said human subject, wherein the subject is a pre-term infant, an infant, a child or an elderly person.

Applicant argues (page 14 of Response filed on 10/31/2007) that Levitt et al do not teach administering IL-9 antibody to a patient for treating or ameliorating a respiratory infection as recited in claim 1. Applicants argue that the rejection for claim 5 would have been proper but now claim 5 recites a specific antibody with its sequence identifier number which would not be anticipated by Levitt et al.

Applicant's arguments have been fully considered but they are not persuasive because the reference Levitt et al teaches a method of alleviating asthma by administering an IL-9 antagonist to a patient (claims 1-5). Levitt et al contemplate using an antibody that specifically binds IL-9/IL-9 receptor can optionally provide complete protection from antigen induced airway hyperresponsiveness and inflammation (column 10, lines 51+, col., lines 14+, claim 10).Levitt et al teach that asthma, which is a disorder or symptom, may be a result of viral infection (column 1, lines 57+). Therefore, treating asthma by administering an antibody specific to IL-9 would inherently treat a symptom which is due to a viral infection. Levitt et al directs their finding on Cogswell et al which clearly establishes association with asthma and viral infection. It is noted that Cogswell et al (Ref. 24) is applied to support the state of art and not as a prior art. Levitt et al teach that about 15% children and 5% adults suffer with asthma (col. 1, lines 58+). Therefore, they contemplate using a patient population which includes children and adults. Levitt et al teach that an antibody can

be administered by one or more of routes selected from the group consisting of intravenous, intra-peritoneal, inhalation, intramuscular, subcutaneous or oral (claim 6, 8-9). Therefore, the prior art explicitly or implicitly anticipates the instant invention as drawn to treating a symptom of respiratory infection.

Since every patent is presumed valid (35 U.S.C. 282), and since that presumption includes the presumption of operability (Metropolitan Eng. Co. v. Coe, 78 F.2d 199, 25 USPQ 216 (D.C.Cir. 1935), examiners should not express any opinion on the operability of a patent. Affidavits or declarations attacking the operability of a patent cited as a reference must rebut the presumption of operability by a preponderance of the evidence. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8 and 15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Levitt et al. (2001) as applied to claims 1 and 24, in view of Skoner (Pediatrics 109: 381-392, 2002) for the reasons of record on page 10-11 of the Office Action of 5/1/2007.

Claims 8 and 15 are broadly drawn to a method of treating or ameliorating a respiratory infection or a symptom thereof in a human subject suffering therefrom, wherein the method of claim 1 further comprises administering an effective amount

of one other therapy (i.e. a leukotriene modifier montelukast such as zafirlukast, pranleukast or zileuton) (claims 8), and wherein the said therapy is an anti-inflammatory agent (claim 15).

Applicant argues (page 17 of Response filed on 10/31/2007) that neither Levitt et al not Skoner teach the limitations of the amended claims 3-5.

Applicant's arguments have been fully considered but they are not persuasive because claims 8 and 15 depend from claim 1 and claim 1 does not include the limitations recited in claims 3-5. Therefore, the rejection is maintained. However, Applicant's amendment of claim 1 to include the limitations of claim 3, 4 or 5 could overcome with this rejection.

Claims 9 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Levitt et al. (2001) as applied to claim 1 and 8 and further in view of Elliott, Michael (Phil. R. Soc. Lond. 356: 1885-1893, 2001).

Claims 9 and 10 are further drawn to a method of treating or ameliorating a respiratory infection or a symptom thereof in a human subject suffering therefrom, said method comprising administering an effective amount of an IL-9 antagonist wherein the respiratory infection is a viral infection (claim 9) and wherein the viral infection is an influenza virus infection (10).

Applicant argues (page 18 of Response filed on 10/31/2007) that the references Levitt et al and Elliott teach treating unrelated disorders: Levitt et al teaches asthma and Elliott teaches influenza. Therefore, one of the skill in the art

would not be able to combine the teachings of Levitt and Elliott to arrive the method of claim 1.

Applicants arguments have been fully considered but they are not persuasive because Levitt et al teach that IL-9 plays role in a pathogenesis of atopic allergy, including bronchial hyperresponsiveness, asthma, and related disorders (column 8) and further Levitt teaches that asthma is a disorder (symptom) and because viral infection strongly influence asthma, they teach treating a symptom of viral infection. Elliott teaches that influenza is highly contagious respiratory tract infection that is caused by influenza type A and B viruses. They teach treating respiratory infection caused by influenza virus by administering a neuraminidase inhibitor known as Zanamivir (page 1885). Elliott teaches that the intranasal administration of zanamivir in humans infected with influenza virus reduces influenza related complications 17-31% compare with placebo (page 1889). Therefore, it would have been prima facie obvious to one of ordinary skill in the art to at the time of invention was made to include administration of a neuraminidase inhibitor such as zanamivir in combination with an anti-IL-9 antagonist in a patient having respiratory infection associated with influenza virus.

In response to applicant's argument that Levitt et al and Elliott is nonanalogous art and that one of the skill in the art would not be able to combine the teachings of Levitt and Elliott to arrive the method of claim 1, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was

concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Levitt et al teach treating asthma using an antagonist of IL-9 and Elliott teaches respiratory infections caused by influenza virus by administering zanamivir. Therefore, one of ordinary skill in the art would include the administration of a neuraminidase inhibitor such as zanamivir in combination with an anti-IL-9 antagonist in a patient having respiratory infection associated with influenza virus.

Claims 37-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 3-4 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra
Art Unit 1646
09 April 2008
Fax: 571-273-2922

/Robert Landsman/
Primary Examiner, Art Unit 1647